ALSTON&BIRD LLP

TO: OMB-OIRA

FROM: Small Business Cigar Coalition

DATE: November 4, 2015

RE: Talking Points Re: FDA Deeming-Final Rule

A. Introduction

- Non-Premium Lower-Priced Products. Small Business Cigar Coalition (SBCC) represents approximately15 U.S. manufacturers of tobacco and cigar products. These cigar products generally include cigarillos and other smaller sized non-filtered, filtered and tipped, non-flavored and flavored, natural leaf hand-rolled and machine-made products. These companies rely on new products to compete and meet consumer demand.

- Mostly Small Businesses. All these manufacturers are small businesses (350 employees or less). These products are most commonly made, distributed and sold by fewer than 300 small businesses that together account for more than 170,000 jobs in cigar related businesses many in depressed rural areas. The Dunham Study estimates that 75% of small tobacco manufacturers will fail following implementation of FDA Deeming Rule (118 small businesses remaining) v. 8% failure rate for large firms (48 or 52 will remain).

- Small Percentage of Tobacco Market. Machine-made smaller-sized cigars constitute less than 2% of total U.S. tobacco sales annually. They are most commonly used by older adult smokers without the resources required to purchase more expensive hand-rolled premium cigars. Their use has generally not increased since a peak in 2004 despite prices that are significantly lower than cigarettes.

- Not Interchangeable. Their use is not interchangeable with cigarettes, or this small market share would have increased through lower priced products. Cigars are required by TTB to use low-sugar air-cured burley tobacco v. higher-sugar flue-cured Oriental tobacco—making harsher product that is generally not inhaled.

- Underage Use Declining. FDA, CDC Office of Smoking and Health, and the public health community have tried to create a “public health crisis” building pressure to publish this rule by arguing the youth usage has increased dramatically. Underage use of flavored smaller-sized cigars have actually decreased significantly since 2002 based on sales experience, TTB removal reports and more accurate SAMHSA national surveys.

- Under-Aged Use Remains Small. CDC, the Campaign for Tobacco Free Kids (CFTFK) and individual researchers from FDA and CDC continue to publish (on their own) surveys seeking these national headlines. When analyzed, their methodology demonstrates significant limitations, inaccuracies and bias: including: 18+ year olds reported as "youth or underage smokers;" self-reported responses listing cigarette brands as cigar brands; single puff in last 30-days included as cigar smokers; programmed cigarette and cigar responses; etc. Actual rates of under-aged use of cigars (tried more than 2 days in last 30 days) is approximately 1.2% v. the 11% reported by CDC.

- Base Regulation on Facts. Industry expects FDA's Deeming Rule to be published, but its approach to regulation, especially for traditionally flavored cigar products, should be based on actual facts, not statistical manipulation.

- Allow Reference Standard Predicates. Minor modifications could be made to the SE process, including allowing the construction of reference standard predicate products for companies without access to 2007 predicates.

B. Following Issues Discussed in Last Meeting. SBCC met with OMB-OIRA on November 21, 2013 following publication of the Proposed Tobacco Deeming Rule and made the following major points:

- Grandfather Date for SE Predicates Must Roll Forward. Current comparisons to 2007 "predicate" products impractical and unnecessary. FDA can use its enforcement discretion to move the date forward to a more reasonable date.

- Unreasonable FDA SE Standards. FDA's Center for Tobacco Products (CTP) continues to increase its substantiation standards for scientific information to support a Substantial Equivalence (SE) determination to a level where no small business can afford to maintain even provisional products on the market.

- Small Business Protections Discarded. Small businesses are the most exposed to a total "regulatory quagmire" where little agency restraint has been demonstrated, and all negotiated transition rules and protections for small businesses have been eliminated through unexpected and controversial agency interpretations.

- Inability of Small Businesses to Comply. Deeming a huge number of new products regulated by FDA using the agency's current interpretations could: (1) paralyze the agency; (2) eliminate small businesses and the jobs they create; (3) remove any ability to comply; (4) dramatically increase costs without any improvement of public health; (5) increase consumer costs and reduce consumer choice; and (6) consolidate control of the market to a few large tobacco manufacturers and their cigarette products.

- Tailor Rules to Products Regulated. Tailor TCA implementation provisions to the unique attributes of cigar manufacturing and sale. Do not merely "flip the switch" on TCA requirements for all newly deemed products.

- Reset Compliance Dates. Reset all transition and compliance dates.

- Prioritize Requirements. Prioritize and stagger FDA regulatory requirements.

- Permit Internet Sales; Free Samples. Permit internet sale and free sampling at trade shows and adult-only facilities (e.g., tobacco and cigar shops).

- Preempt State Warning Requirements. Eliminating pregnancy warnings and modifying FTC warnings require federal preemption from inconsistent state labeling requirements.

C. Current Recommendations: Following an additional 2-years of FDA tobacco regulation, we make the following recommendations for the Final Rule:

- Reset Compliance Dates. Reset all transition and compliance dates (since it is 8-10 years later).

- Stagger Compliance Requirements. Allow FDA to use its enforcement discretion to stagger compliance requirements, especially for small businesses—focusing first on manufacturer and product registrations, so FDA can understand the extent and nature of the newly-deemed products it seeks to register—and deploy resources accordingly.

- No "Backdoor" Testing/Bans. Do not let FDA ban or limit Hazardous and Potentially Hazardous Constituents (HPHCs) and characterizing flavors through the "backdoor" bypassing specific TCA provisions using the SE Reporting process (e.g., requiring testing of predicate and "new product" HPHCs and flavors to determine if they are "identical" or raise different questions of public health).

- Don't Shift Safety Burden to Small Manufacturers. FDA should have the burden of proving that cigar flavorings are harmful (e.g., similar to menthol review), not shifting the burden to small manufacturers to prove that flavors are safe (and do not increase initiation or reduce cessation) through expensive time-consuming human clinical research.

- Test Costs Excessive and Wasteful. Cigars are not drugs or medical devices. Manufacturers do not have patents or other exclusivity that can support prices sufficient to pay for human clinical trials (safety of flavorings; modified-risk claims; PMTAs; etc.) or hundreds of head-to-head performance tests. These deemed products do not have accepted testing methodologies. Thus, any additional

testing information requested has proven useless in "comparing apples to oranges" in SE submissions.

- FDA Should Conduct Basic Research. FDA has billions of dollars collected through product user fees to conduct product research. Research protocols should be designed carefully with input sought from industry with valid endpoints to prevent bias.

- Regulatory Guidance Required. There are no generally accepted testing methodologies for cigars—which vary in size, shape, components and smoking patterns. CTP must not require product testing, design controls and quality system manufacturing practices without specific regulations and/or guidance.

- Required SE Information Should be Transparent. CTP should not require the preparation and filing of SE Reports without specific regulations and/or guidance listing the information required to be included in those reports. It is not sufficient to say that small businesses should read PowerPoint slides from webinars or redacted agency review reports to figure this out. Companies learn for the first time about new requirements in a letter which gives them a 30-60-day window to identify, test and provide this information.

- Scale Back Regulations. Scale back attempts to regulate and control every aspect of tobacco manufacture, sale and use (e.g., labeling, quantities, packaging). For example, some states require packaging in larger content sizes which could lead to required FDA SE approvals.

- Exempt Minor Changes. CTP should use existing authority to exempt "minor changes" from the need to file additional SE Reports, and use common sense and logic to determine what changes actually affect the public health and need to be documented. To date, CTP has moved in the opposite direction—actually requiring new SE Reports for each change in component supplier, tobacco blend, brand name, package color/content or product manufacturing process. Cigar contents, blends and manufacturing methods vary much more than cigarettes.

- Fair User Fee Formulas. Ensure that the level of user fees assessed to cigar manufacturers account accurately for the small market share of cigars v. other tobacco products and a small businesses' share within each cigar product category based on TTB unit removals. Require that all products deemed regulated by FDA pay their fair share of industry user fees based on market share of tobacco-derived products, and units sold.